

CLAIMS

- Sub C1*
1. A method of immunizing a vertebrate, said method comprising administering to a vertebrate a DNA transcription unit comprising DNA encoding a desired antigen operatively linked to DNA which is a promoter region, whereby a humoral immune response, a cell-mediated immune response or both is elicited against a desired antigen.
  2. The method of Claim 1, wherein the promoter region of a DNA transcription unit is of nonretroviral origin.
  3. The method of Claim 1, wherein the promoter region of a DNA transcription unit is of retroviral origin.
  4. The method of Claim 1, wherein a desired antigen is capable of eliciting a protective immune response against an infectious agent.
  5. The method of Claim 4, wherein the infectious agent is a virus.
  6. The method of Claim 5, wherein the virus is an influenza virus.
  7. The method of Claim 6, wherein a desired antigen is an influenza virus hemagglutinin.
  8. The method of Claim 5, wherein the virus is a rotavirus.
  9. The method of Claim 5, wherein the virus is simian immunodeficiency virus.

10. The method of Claim 5, wherein the virus is human immunodeficiency virus.
11. The method of Claim 1, wherein the vertebrate is a mammal.
- 5 12. The method of Claim 7, wherein the mammal is a human.
13. The method of Claim 1, wherein the DNA transcription unit, in a physiologically acceptable carrier, is administered to a vertebrate through a route of administration selected from the group consisting of:
- 10 intravenous, intramuscular, intraperitoneal, intradermal and subcutaneous.
14. The method of Claim 1, wherein the DNA transcription unit is administered to a vertebrate by contacting the DNA transcription unit, in a physiologically acceptable carrier, with a mucosal surface of the vertebrate.
- 15 15. The method of Claim 1, wherein the DNA transcription unit is microsphere encapsulated, and is administered to a vertebrate by contacting microsphere-encapsulated DNA transcription unit, in a physiologically acceptable carrier, with a mucosal surface of the vertebrate.
- 20 16. A method of immunizing a vertebrate, said method comprising administering to a vertebrate one or more DNA transcription units, each comprising DNA encoding a desired antigen or antigens operatively linked to DNA which is a promoter region, whereby a humoral immune response, a cell-mediated immune response or
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both is elicited against a desired antigen or antigens.

17. A method of immunizing a vertebrate against an infectious agent, said method comprising administering to a mucosal surface of the vertebrate a DNA transcription unit comprising DNA encoding a desired antigen operatively linked to DNA which is a promoter region, in a physiologically acceptable carrier, thereby eliciting a humoral or cell-mediated immune response, or both, against a desired antigen, whereby the vertebrate is protected from disease caused by an infectious agent.
18. The method of Claim 17, wherein the promoter region of a DNA transcription unit is of nonretroviral origin.
19. The method of Claim 17, wherein the promoter region of a DNA transcription unit is of retroviral origin.
20. The method of Claim 17, wherein the mucosal surface is a respiratory mucosal surface.
- 20 21. The method of Claim 20, wherein the respiratory mucosal surface is a nasal mucosal surface.
22. The method of claim 20, wherein the respiratory mucosal surface is a tracheal mucosal surface.
23. The method of Claim 17, wherein the DNA transcription unit is microsphere encapsulated.
- 25 24. The method of Claim 17, wherein the infectious agent is a virus.

25. The method of Claim 24, wherein the virus is an influenza virus.
26. The method of Claim 25, wherein a desired antigen is an influenza virus hemagglutinin.
- 5 27. The method of Claim 24, wherein the virus is a rotavirus.
28. The method of Claim 24, wherein the virus is simian immunodeficiency virus.
29. The method of Claim 24, wherein the virus is human immunodeficiency virus.
- 10 30. The method of Claim 17, wherein the vertebrate is a mammal.
31. The method of Claim 30, wherein the mammal is a human.
- 15 32. A method of immunizing a vertebrate against an infectious agent, said method comprising administering parenterally to the vertebrate a DNA transcription unit comprising DNA encoding a desired antigen of an infectious agent operatively linked to DNA which is a promoter region, in a physiologically acceptable carrier, thereby eliciting a humoral or cell-mediated immune response, or both, against a desired antigen, whereby the vertebrate is protected from disease caused by the infectious agent.
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33. The method of claim 32, wherein the route of administration is chosen from the group consisting of intravenous, intramuscular, intraperitoneal, intradermal and subcutaneous.
- 5 34. The method of Claim 32, wherein the promoter region of a DNA transcription unit is of nonretroviral origin.
35. The method of Claim 32, wherein the promoter region of a DNA transcription unit is of retroviral origin.
- 10 36. The method of Claim 32, wherein the infectious agent is a virus.
37. The method of Claim 36, wherein the virus is an influenza virus.
- 15 38. The method of Claim 37, wherein a desired antigen is an influenza virus hemagglutinin.
39. The method of Claim 36, wherein the virus is a rotavirus.
40. The method of Claim 36, wherein the virus is simian immunodeficiency virus.
- 20 41. The method of Claim 36, wherein the virus is human immunodeficiency virus.
42. The method of Claim 32, wherein the vertebrate is a mammal.
- 25 43. The method of Claim 42, wherein the mammal is a human.

*Sub C4*

44. A method of immunizing a mammal against an immunodeficiency virus, said method comprising administering to the mammal a DNA transcription unit comprising DNA encoding an antigen of the immunodeficiency virus operatively linked to DNA which is a promoter region, in a physiologically acceptable carrier, and thereby eliciting a humoral or cell-mediated immune response, or both, against the desired antigen, whereby the vertebrate is protected from disease caused by the immunodeficiency virus.

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45. The method of Claim 44, wherein the DNA transcription unit is administered in combination with one or more additional DNA transcription units, each comprising DNA encoding a different antigen of the immunodeficiency virus operatively linked to a promoter region.

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46. The method of Claim 45, wherein the antigens of the transcription units represent different subgroups of the immunodeficiency virus.

47. The method of Claim 45, wherein the antigens of the transcription units represent different phases of infection of the immunodeficiency virus.

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48. The method of Claim 45, wherein the antigens of the transcription units represent different tissue tropisms of the immunodeficiency virus.

49. The method of Claim 45, wherein the antigens of the transcription units represent different routes of transmission of the immunodeficiency virus.

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50. The method of Claim 44, wherein the immunodeficiency virus is simian immunodeficiency virus.
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51. The method of Claim 44, wherein the immunodeficiency virus is human immunodeficiency virus.
- 10 52. A method of immunizing a mammal against an influenza virus, said method comprising administering to the mammal a DNA transcription unit comprising DNA encoding an antigen of the influenza virus operatively linked to DNA which is a promoter region, in a physiologically acceptable carrier, and thereby eliciting a humoral or cell-mediated immune response, or both, against the desired antigen, whereby the vertebrate is protected from disease caused by the influenza virus.
- 15 53. The method of Claim 52, wherein the DNA transcription unit is administered in combination with one or more additional DNA transcription units, each comprising DNA encoding a different antigen of an influenza virus operatively linked to a promoter region.
- 20 54. The method of Claim 53, wherein the different antigens are from different subtypes of influenza.
55. The method of Claim 53, wherein the different antigens are from different subgroups of influenza.
- 25 56. The method of Claim 53, wherein the different antigens are from different subgroups and different subtypes of influenza.
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